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Re: Application No. - 10/057,116

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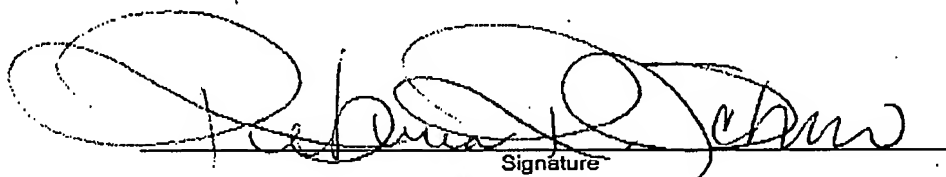
Application No.: 10/057,116

Attorney Docket No.: AB-165U

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JUN 04 2007

Serial No.: 10/057,116

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application: Todd K. Whitehurst et al.
Application No.: 10/057,116
Filed: January 24, 2002
Title: "Fully Implantable Neurostimulator for Peripheral Nerve Stimulation as a Therapy for Chronic Pain"

Confirmation No.: 1864
Examiner: SCHAETZLE, Kennedy
Group Art Unit: 3766

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF REPLY BRIEF

Sir:

Transmitted herewith is the Reply Brief with respect to the Examiner's Answer mailed on April 4, 2007.

This Reply Brief is being filed pursuant to 37 CFR 1.193(b) within two months of the date of the Examiner's Answer.

(Note: Extensions of time are not allowed under 37 CFR 1.136(a))

(Note: Failure to file a Reply Brief will result in dismissal of the Appeal as to the claims made subject to an expressly stated new ground rejection.)

No fee is required for filing of this Reply Brief.

If any fees are required please charge Deposit Account 18-0013.

(X) I hereby certify that this paper is being transmitted to the Patent and Trademark Office facsimile number (571) 273-8300 on June 4, 2007

Number of pages: 14

Signature: 

Rebecca R. Schow

Respectfully submitted,

By: 

Steven L. Nichols (Reg. No.: 40,326)
Attorney/Agent for Applicant(s)
Telephone No.: (801) 572-8066
Date: June 4, 2007

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10/057,116

JUN 04 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent Application of

Todd K. Whitehurst et al.

Application No. 10/057,116

Filed: January 24, 2002

For: "Fully Implantable Neurostimulator for
Peripheral Nerve Stimulation as a
Therapy for Chronic Pain"

Group Art Unit: 3766

Examiner: SCHAETZLE, Kennedy

REPLY BRIEF

Mail Stop Appeal Brief - Patents
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P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Reply Brief under Rule 41.41 (37 C.F.R) in response to the Examiner's Answer of April 4, 2007 (the "Examiner's Answer" or the "Answer"). In Section 10, the Answer contains a response to some of the arguments made in Appellant's brief. Appellant now responds to the Examiner's Answer as follows.

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Claim 4:

Claim 4 recites:

A method for treating a patient with chronic pain, comprising:
identifying a patient experiencing sensations of chronic pain;
providing at least one leadless stimulator having at least two electrodes;
implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and
delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;
wherein the at least one peripheral nerve comprises at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve.
(emphasis added).

Appellant has disclosed and claimed new methods for treating a patient with particular types of chronic pain based on delivering stimulation pulse to specific nerve sites. For example, in claim 4, the specific nerves stimulated include "at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve." As Appellant has previously pointed out, the cited prior art fails to teach or suggest the claimed method including stimulation at any of these specific nerve sites for the treatment of chronic pain.

The Examiner's Answer attempts to explain away this deficiency of the prior art as follows. "Schulman et al. do not explicitly discuss intercostal and occipital nerves because they clearly do not wish to limit their invention to any one particular nerve or neural pathway as the

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intent of the device is to permit a wide variety of applications and treatments to be realized.”

(Answer, p. 6). This argument is completely unreasonable.

Even the most novice practitioner in the patent field knows that it is the claims that define the scope of a patent. It would not have limited the scope of the Schulman patent application to provide examples of the specific nerves to be stimulated. Such detail is to be expected in the disclosure of a patent application, if the applicant actually had possession of that information.

Moreover, even if this were a legitimate argument, which it isn't, there is nothing that precludes the Examiner from citing some other prior art reference that teaches or suggests stimulation of the specific nerve sites claimed by Appellant for the treatment of chronic pain. In fact, in the present instance, the Examiner did cite a secondary reference, Novak, which did list some specific nerve sites at which stimulation could be provided. However, Novak also failed to teach or suggest the specific nerve sites claimed by Appellant, thus strengthening the argument that Appellant's teachings are beyond the scope of the prior art.

The Answer further misunderstands and takes exception to the arguments of the Appeal Brief as follow. Appellant's Brief stated that

the Action appears to take the position that because the prior art teaches stimulating certain nerves to treat non-chronic pain, it would be obvious to stimulate any other nerve site to treat chronic pain. (Action of 7/14/06, p. 5). This is clearly reading far too much into the prior art. One of ordinary skill in the art, e.g., a physician, would never make such a leap in reasoning.

(Appellant's Brief, p. 10).

This statement was made primarily with reference to the fact that the Examiner has been unable to cite any prior art that teaches stimulation at the specific nerve sites claimed, but nevertheless improperly holds stimulation at those sites obvious.

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Apparently not understanding the need to actually demonstrate the recitations of the claim in the prior art in order to make a rejection, the Examiner's Answer focuses in this regard on the distinction between chronic and non-chronic pain. (Answer, p. 7). This is entirely beside the point that the Examiner has failed to cite any prior art that teaches applying stimulation pulses at the specific nerve sites claimed to treat pain.

The Answer argues that "[t]here is nothing in either prior art reference that precludes chronic pain treatment or that limits treatment to only non-chronic situations or specific peripheral nerves." (Answer, p. 7). This, again, is wholly irrelevant. Just because the prior art references don't explicitly preclude the claimed subject matter does not remotely mean that the references actually teach the claimed subject matter. A reference describing a radio does not preclude chronic pain treatment or preclude stimulation of specific peripheral nerves. It also doesn't teach or suggest any such thing either.

Again, we come back to the same point. The Examiner has failed to cite any prior art that teaches applying stimulation pulses at the specific nerve sites claimed to treat pain.

The Examiner's Answer seems to take the position that when pain is experienced it is a simply and straightforward matter to identify the nerve sites responsible and stimulate those nerves sites to treat the pain. (Answer, p. 8). This simplistic view is incorrect. Frequently, the relationship between a particular pain symptom experienced by a patient and its neurological antecedent, if any, is entirely unclear.

An obvious example is phantom limb syndrome in which amputees experience sensations, usually including pain, from a missing limb. (<http://www.medterms.com/script/main/>

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art.asp?articlekey=9111). According to the reasoning in the Examiner's Answer, this condition is readily treated by stimulating the nerves of the missing limb.

The point is that there is not such a clear connection between sensations of pain and specific nerve sites in the body as the Examiner's Answer would have it. Rather, those of skill in this art are aware that applying electrical stimulation to different portions of the nervous system can have unintended and unpredictable effects.

If the prior art had discovered stimulation at the specific nerve sites recited in claim 4 for the treatment of chronic pain, the Examiner is invited to cite prior art that actually contains such a teaching.

Under the analysis required by *Graham v. John Deere*, 383 U.S. 1 (1966), the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue. In the present case, the scope of the prior art, as evidenced by the prior art of record, does not appear to include the application of stimulation pulses to the specific nerve sites claimed by Appellant for the treatment of chronic pain. That being the case, the differences between the prior art and the claim at issue are clear and substantial. Appellant has disclosed and has claimed nerve sites which, unknown to the prior art, can be effectively stimulated for the treatment of specific types of chronic pain.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). Schulman does not teach or suggest a method of stimulating nerves that include any of the nerves now recited in claim 4. Novak likewise does not teach or suggest a method including stimulation of any of the nerves now

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recited in claim 4. Consequently, the applied prior art, taken alone or in combination, does not teach or suggest the method of claim 4.

It is incumbent upon the Office to cite prior art that actually teaches the subject matter of Applicant's claims. M.P.E.P. § 706.02(j). In the present case, the prior art of record does not teach or suggest the method of claim 4 including the specific stimulation sites recited for the purpose of treating chronic pain. For at least these reasons, the rejection of claim 4 should not be sustained.

Claim 8:

Claim 8 recites:

A method for treating a patient with chronic pain, comprising:
identifying a patient experiencing sensations of chronic pain;
providing at least one leadless stimulator having at least two electrodes;
implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and
delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the chronic pain is located in one or both lower limbs, and the at least one stimulator is implanted adjacent to at least one nerve fiber of a common peroneal nerve, a common peroneal nerve branch, a sciatic nerve, a sciatic nerve branch, a saphenous nerve, a saphenous nerve branch, a posterior cutaneous nerve, a posterior cutaneous nerve branch, a sural nerve, a sural nerve branch, an obturator nerve, an obturator nerve branch, a femoral nerve, a femoral nerve branch, a lateral cutaneous nerve, and a lateral cutaneous nerve branch.

(emphasis added).

Again, the Examiner has failed to provide prior art that actually teaches or suggests the method of claim 8, including implanting a leadless stimulator at the specific nerve sites recited.

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For the reasons given above, the Examiner cannot simply assume away this subject matter in a rejection based on prior art that does not even mention the specific nerve sites of the treatment method recited by Appellant.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 8 should not be sustained.

Claim 27:

Claim 27 recites:

A method for treating a patient with chronic pain, comprising:
providing at least one leadless stimulator having at least two electrodes;
implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters;
delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient; wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;
transmitting data from a transmitter of said stimulator to an external device; and
transmitting said stimulation parameters to said external device.
(Emphasis added).

In contrast, the cited combination of prior art fails to teach or suggest a method in which an implanted stimulator transmits its stimulation parameters to an external device. In this regard, the Examiner's Answer cites Nelson at col. 2, lines 39-53. (Answer, p. 10). This portion of Nelson reads as follows:

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After the implantation of an IMD [Implantable Medical Device], for example, a cardiac pacemaker, clinician involvement with respect to the IMD has typically only begun. The IMD usually cannot be merely implanted and forgotten, but must be monitored for optimal results, and may require occasional adjustment of certain parameters or settings, or even replacement, in response to or in anticipation of changes in patient condition or other environmental factors, or based on factors internal to the device. IMDs may also contain logic devices such as digital controllers, which may need to undergo firmware or software upgrades or modifications. In addition, information about the IMD may be gathered for treatment or research purposes. *For example, many IMDs are capable of storing certain state information or other data regarding their operation internally in addition to physiological data.*

(Nelson at col. 2, lines 39-53) (emphasis added).

The Answer notes that this portion of Nelson states that the IMD stores data "in addition to physiological data." (Answer, p. 10). The Answer then speculates that such additional data would naturally include the claimed stimulation parameters. However, the Answer neglects the obvious fact that Nelson merely states that the IMD stores such data. Nelson does not teach or suggest transmitting this data to an external device -- nor that this data would include stimulation parameters.

Historically, it has been the practice to periodically explant implanted stimulators after an experiment has been completed, after the power source has been depleted, or for any number of other reasons. At the time of the Nelson reference, one of skill in the art would likely have assumed that any data needed from the IMD would be obtained by explanting the IMD to retrieve the data. One of skill in the art certainly need not have made the leap the Examiner makes that because the IMD stores data in addition to physiological data that the additional data includes stimulation parameters and that the IMD somehow has the ability to transmit such data to an external device, despite there being no mention of such a teaching in the Nelson reference.

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Again, the Examiner wants to reject a claim without having provided prior art that actually teaches the subject matter claimed. Again, under the analysis required by *Graham v. John Deere*, 383 U.S. 1 (1966), the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue. In this instance, the scope of the prior art has not been shown to include the claimed method comprising transmitting stimulation parameters from an implanted stimulator to an external device. This substantial difference between the claimed method and the demonstrated scope of the prior art makes it clear that Schulman and Novak cannot support a rejection of claim 27 under *Graham*.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 27 should not be sustained.


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In view of the foregoing, it is submitted that the final rejection of the pending claims is improper and should not be sustained. Therefore, a reversal of the Final Rejection of July 14, 2006 is respectfully requested.

Respectfully submitted,

DATE: June 4, 2007


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Rebecca R. Schow